MAR 21 2000

K000376

SPECIALTY

ULTRAVISION INC.

510(k) Summary

Submitter Information:

Company: Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Garold L. Edwards, O.D., F.A.A.O.
Vice President, Technical Affairs

Telephone: (408) 341-0700
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Date Prepared: 3 February 2000

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: Specialty 42 (hefilcon A) Hydrophilic Contact Lens for Daily Wear
Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The predicate devices are the Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses for Daily Wear, cleared under 510(k) K973192. These lathe-cut devices were selected as the predicate devices because they are made from the same polymer as the current device. Furthermore, the lenses will be manufactured in the same facility, using the same lens designs and under the same Quality System as the predicate devices.

Description of Devices:

The Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses for Daily Wear are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The lens material (hefilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and n-vinyl-2-pyrrolidone (NVP) cross-linked with ethyleneglycol dimethacrylate (EGDMA), using AIBN as the initiator. The lens contains 42% water by weight. The Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses for Daily Wear are tinted using an in-monomer tinting process with D&C Green #6 (1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione), which is approved for coloring contact lenses under 21 CFR § 74.3206.

Comparison to Predicate Device

PARAMETER	**Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lens for Daily Wear (lathe-cut)**	**Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lens for Daily Wear (manufactured using a molding process)**
material	hefilcon A	hefilcon A
material classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1
indication for use	Myopia, hyperopia and astigmatism	Myopia, hyperopia and astigmatism
water content	42%	42%
light transmittance	98%	98%
Dk (35° C)	13.250×10^{-11}	13.333×10^{-11}
powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
color	clear or blue visibility	clear or blue visibility
refractive index	1.417	1.415
specific gravity	1.031	1.041
Method of manufacture	Lathe-cut	Molded
Method of packaging	Glass vials	Blister Packaging

Indications for Use:

The Specialty 42 and the Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes.

Eyecare practitioners may prescribe the lenses for daily wear in a Frequent Replacement Program with scheduled replacement. The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed on the Specialty 42 and Specialty T-42 Toric lenses. Physicochemical testing showed the lenses to be substantially equivalent to the predicate devices. Leachability studies demonstrated that the dye is stable and does not leach out of the lens matrix. Cytotoxicological testing confirms that the molded lens polymer is not cytotoxic. Cytotoxicity, systemic injection and primary ocular irritation studies established that the blister material is non-toxic and does not produce ocular irritation.

Conclusions:

Information submitted in the 510(k) establishes that the Specialty 42 and Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lenses for Daily Wear have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2000

Garold L. Edwards, O.D., F.A.A.O.
Vice President, Technical Affairs
Specialty ULTRAVISION, Inc.
307 Orchard City Drive
Suite 100
Campbell CA 95008

Re: K000376
Trade Name: Specialty 42 (hefilcon A) Hydrophilic contact Lens for Daily Wear And
Specialty T-42 Toric (hefilcon A) Hydrophlic Contact Lens for Daily Wear
(clear and visibility tinted with D&C Green #6, cast-molded)
Regulatory Class: II
Product Code: 86 LPL
Dated: February 3, 2000
Received: February 7, 2000

Dear Dr. Edwards:

This letter corrects our substantially equivalent letter of March 21 2000, regarding the document number.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic, Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

Device Names:

Specialty 42 (hefilcon A) Hydrophilic Contact Lens for Daily Wear
Specialty T-42 Toric (hefilcon A) Hydrophilic Contact Lens for Daily Wear

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

Ey Ge, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K020376